

TABLE 49

Determination of Respirable Dose, 1 mg/mL Fentanyl							
Test		Method			Specification		
Assay of Fentanyl in sublingual spray samples Determination of respirable dose in fentanyl sublingual spray by cascade impaction		Described in Example 17			Report Results		
					Report Results		
CI Run	Sample	Fentanyl (µg/dose)	Particle Size groupings	Groupings percent	Average Shot weight (mg)	Total Mass <9 µm (µg)	Respirable dose <9 µm (µg)
1	Globe	76.5694	≥9 µm	96.4	85.4	2.9	3.6
	Plate 0	0.5479					
	Plate 1	0.6228	9 µm > X ≥ 5.8 µm	0.8			
	Plate 2	0.4746	<5.8 µm	2.9			
	Filter	1.8149					
2	Globe	78.6941	≥9 µm	96.6	84.0	2.8	3.4
	Plate 0	0.6746					
	Plate 1	0.6217	9 µm > X ≥ 5.8 µm	0.8			
	Plate 2	0.5000	<5.8 µm	2.6			
	Filter	1.6740					
3	Globe	78.0529	≥9 µm	97.1	85.3	2.3	2.9
	Plate 0	0.5082					
	Plate 1	0.5429	9 µm > X ≥ 5.8 µm	0.7			
	Plate 2	0.4185	<5.8 µm	2.2			
	Filter	1.3596					
Average percent respirable dose							3.3

Many other variations of the present invention will be apparent to those skilled in the art and are meant to be within the scope of the claims appended hereto, including but not limited to the particular unit dose or bi-dose devices and the particle size range of fentanyl produced, as well as other numerical parameters described in the examples, and any combination thereof.

What is claimed is:

1. A method of treating pain comprising sublingually administering a liquid spray formulation in the form of dis-

crete liquid droplets having a mean diameter of at least about 10 microns to a human patient experiencing pain, said liquid spray formulation comprising an effective amount of fentanyl, a free base or a pharmaceutically acceptable salt thereof, or derivative thereof, dispersed in a pharmaceutically acceptable liquid carrier.

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